HFI-35 (PURGED)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1227B

FEB 27 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Ruy S. Baumer
President
Baumer Ltda.
381 Av. Prefeito Antonio Tavares Leite
Mogi Mirim - SP- 13800-000
BRASIL

Dear Mr. Baumer:

As a result of our reinspection of your facility located in Mogi Mirim, Brasil, 12/2-6/96, we have determined that serious GMP violations continue for sterile products.

The inspection revealed that sterile devices are adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and implement specification control measures to assure that the design basis for the device and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example:

   a. Package seal strength studies have not been completed.

   b. Package integrity studies have not been completed.

2. Failure to have written procedures describing processing controls necessary to assure conformance to specifications and to conduct processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b). For example: There are no written procedures for reviewing bioburden test results. The tests are not available and have not been reviewed to verify that the bioburden is less than 10^6 as required by the validation of the sterilization cycle.

3. Failure to control environmental conditions, such as ventilation, air pressure, filtration, and airborne contamination to prevent contamination of the device and to provide proper conditions for each of the operations performed, as required by 21 CFR 820.46. For example:

   a. Ventilation, air pressure, and filtration are not controlled in the packaging room.

   b. Particle shedding material was being used to wipe the implants with an alcohol solution just prior to their being sealed.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Non-sterile products under cleared 510(k)s K930966, K930967, K930969, K930970, and K930972 appear to be acceptable. These devices will be removed from automatic detention, clearance of premarket submissions will not be deferred, and Federal agencies may take this into account when considering the award of contracts.

You should take prompt action to correct the deficiencies identified on the FDA-483 immediately. Failure to promptly correct these deviations may result in the detention of your sterile devices without physical examination upon entry into the United States.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any

underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the following individual:

James W. Eisele
U.S. Food and Drug Administration
CDRH, Office of Compliance
Division of Enforcement III
2098 Gaither Road
Rockville, Maryland 20850
U.S.A.

Sincerely yours,

Gladys Rodriguez for.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health